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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,804	12/03/2001	Laszlo Otvos	WST91BUSA	8353

270 7590 12/27/2004

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,804

Applicant(s)

OTVOS, LASZLO

Examiner

Hope A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74, 76, 79, 81-84, 87, 90-101, 103-110 and 113-186 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74, 76, 79, 81-84, 87, 90-101, 103-110, 113-186 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/30/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the Office Action mailed May 2, 2004, on September 13, 2004, is acknowledged.
2. Claims 1-73, 75, 77-78, 80, 85-86, 88-89, 102 and 111-112 have been canceled. Claims 140-186 have been added. Claims 74, 76, 79, 81-84, 87, 90-101, 103, 105-110, 113-115 and 118-139 have been amended. Claims 74, 76, 79, 81-84, 87, 90-101, 103-110, 113-186 are pending and are under examination. Claim 84 previously withdrawn as amended is rejoined.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The following grounds of objection/rejection are or remain applicable:

Claim Objection

5. Claims 90, 92 and 99 are objected to because of the following informalities:

For clarity it is suggested that claim 90 is amended to recite "wherein said additional amino acids", instead of "wherein an additional amino acids of (d)".

Art Unit: 1653

Claim 92 is objected to because the claim provides a Markush list which is separated by semi-colons, it is suggested that commas are used, see for example claim 91.

For clarity it is suggested that the term "optionally" is deleted from claim 99, because it is unclear whether the signal will occur with the interaction that is recited as being optional.

Correction of the above is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 74, 76, 83, 84, 115-119, 136-139 and 160-186 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 160 and the dependent claims hereto are directed to multivalent composition and there is no support for said multivalent composition in the instant specification (see claims 74, 76, 83, 84, 115-119, 136-139 and 160-186). It is suggested that applicant delete the above phrase in the claims and instead claim the composition previously examined. Therefore, this is a new matter rejection.

Art Unit: 1653

7. Claims 74, 76, 79, 81-84, 87, 90-101, 103-110, 113-186 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for a peptide contained in SEQ ID NO:1, for example, does not reasonably provide enablement for said sequence being modified with any naturally-occurring amino acid and unnatural amino acids for the reasons stated in the previous office action.

Response to Applicant's Arguments:

Applicant's response filed on September 13, 2004 state that "there are only 20 naturally occurring amino acids, any modification in the chemical structure of the amino acid, such as by substitution of another chemical group, like an alkyl, a sugar, etc. creates an unnatural amino acid" (see page 28 of the response). However, the instant specification is not enabled for all the possible natural and unnatural amino acids that exist. Furthermore, the modifications contemplated may not result in a protein having the desired activity. In addition, the claims are directed to "a portion of SEQ ID NO:1", see for example claim 143 and there is no indication as to what part of SEQ ID NO:1 is conserved or if function is retained with the modifications encompassed in the claims. As stated in the previous office action the prior art recognizes that substitutions within a protein's sequence can have deleterious effects with regard to the protein's structure/function relationship. Applicant's comments on pages 27-30 of the response are noted, however, are not persuasive, because the issue in this case is the breadth of the claims in light of the predictability of the art as determined by the number of working

Art Unit: 1653

examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decision of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Therefore, absent direction/guidance regarding whether the structure of the polypeptide can tolerate the modifications contemplated a non-functional protein may result and one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. Thus, the rejection remains.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 74, 76, 79, 81-84, 87, 90-101, 103-110, 113-186 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 113 lacks antecedent basis for the recitation of "The composition according to claim 143" as claim 143 is directed to a peptide.

Claim 114 is indefinite for the recitation of "The composition according to claim 160 which is a dimer", as the peptides recited in claim 160 is the dimer not the composition *per se*, which comprises the peptides.

Claim 140 is confusing because it is not clear what the modifications are, for example, is the modification the insertion of a dipeptide? See also claim 160. The dependent claims hereto are also included.

Response to Applicant's Arguments:

Applicant's arguments on page 31 have been considered. However, note that new grounds of rejections have been instituted based on applicant's amendments to the claims for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 103 and 140 are rejected under 35 U.S.C. 102(b) as been anticipated over Bulet et al. (WO9405787, September 6, 1994).

Bulet et al. teach the claimed peptide (SEQ ID NO:1) and the formula contained in instant application: R1-Asp-Lys-Gly-X-Y-Leu-Pro-Arg-Pro-Pro-Arg-Pro-Ile-Tyr-X'-Y'-R2 with a 100% sequence identity and peptides that are not glycosylated (claim 140; abstract; and page 1, line 32). The sequence taught by Bulet et al. is "VDKGSYLPRPTPPRPIYNRN" wherein R1 is valine (a positive moiety), X is serine, Y is tyrosine, X' is asparagine and Y' is arginine as set forth in the instant application. Thus the dipeptides "ser-tyr" and "asn-arg" (claim 103) are taught by the reference. Bulet et al. teach that the entire peptide is not glycosylated, therefore the threonine is necessarily not glycosylated (see page 1, line 32 of the reference). Thus, the limitations of the claims are met by the reference.

Response to Applicant's Arguments:

Applicant's response on pages 31-33 indicate that the cited art of record is not relevant as Bulet's peptides involves substitutions on the glycosyl group and that Bulet discusses a variety of non-pyrrhocoricin sequences. This argument is not persuasive because the structure taught by Bulet is identical to the formula set forth in claim 140, thus anticipates the claimed peptide. Therefore, the rejection of record remains for the reasons stated above.

Conclusion

10. No claims are allowable.

11. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

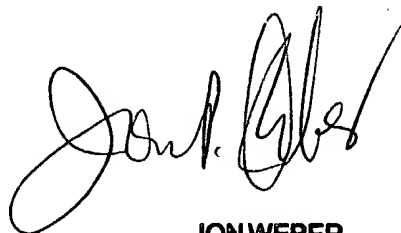
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS *HR*

Patent Examiner *12/20/04*

A handwritten signature in black ink, appearing to read "Jon Weber", with a large, sweeping flourish extending from the end of the name.

JON WEBER
SUPERVISORY PATENT EXAMINER